



**TO: Physicians and other Healthcare Providers** 

# Please distribute a copy of this information to each provider in your organization.

Questions regarding this information may be directed to the following Region IV health officers:

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### **Alert categories:**

**Health Alert:** conveys the highest level of importance; warrants immediate action or attention.

**Health Advisory:** provides important information for a specific incident or situation; may not require immediate action.

**Health Update:** provides updated information regarding an incident or situation; no immediate action necessary.

### HEALTH UPDATE February 23, 2016

## Clinical Guidance on Meningococcal B Vaccine



#### Washington State Vaccine Advisory Committee recommendations

In October 2015 the ACIP recommended serogroup B meningococcal vaccine (MenB) for patients at high risk for this disease and for outbreak control, but left it to providers' discretion whether or not to advise it for others.

- This permissive recommendation is specifically for MenB vaccine.
   (<a href="http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6441a3.htm">http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6441a3.htm</a>)
- The MenB vaccine recommendation differs from the ACIP recommendation for meningococcal conjugate ACYW vaccine (MCV4). MCV4, which does not include serogroup B, is routinely recommended for all persons 11 through 18 years of age. (http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm)

Permissive recommendations may be challenging to implement because they require providers to consider the relevant evidence, formulate their advice and communicate it to their patients and their parents. Some members of the Vaccine Advisory Committee believe providers may have an ethical obligation to inform patients and parents of the availability of the meningococcal B vaccine, even if they would advise limiting its use to those at high risk for meningococcal B disease.

The Washington State Vaccine Advisory Committee is providing this guidance to:

- 1. Give providers current information on the incidence of meningococcal B disease in Washington State.
- 2. Assist providers with formulating their own advice about use of this vaccine in those who are not at high risk for meningococcal B disease.
- 3. Facilitate providers' communication with parents and patients about this vaccine.

#### **Summary of Meningococcal B Vaccination Recommendations:**

- Persons ≥10 years of age with certain rare health conditions that put them at increased risk for meningococcal B disease and its complications should be routinely vaccinated (see detail below).
- In addition, patients 16 through 23 years of age <u>may be vaccinated</u> with meningococcal B vaccine (preferably at 16 through 18 years of age) to provide short-term protection against most strains of serogroup B meningococcal disease.

#### **Suggestions for Talking with Parents:**

Consider using the following language in your discussion with families of children who do not have conditions that put them at high risk for meningococcal B disease:

- Meningitis B vaccine is recommended for those at high risk for meningococcal B disease.
- Your child is not at high risk.
- I do not routinely recommend meningococcal B vaccine to children who are not at high risk. However, I will give your child the vaccine if you want him/her to have it.

The ACIP agreed that historically low levels of disease, limited data about the lasting effectiveness of the vaccine and potentially high costs do not warrant routinely vaccinating all children with the meningococcal B vaccine.

The vaccine should be administered to:

- Persons ≥10 years of age with certain rare health conditions that put them at increased risk for meningococcal B disease and its complications, including:
  - Persons with persistent complement component deficiencies.
  - Persons with anatomic or functional asplenia, including sickle cell disease.
  - Microbiologists routinely exposed to isolates of Neisseria meningitidis.
  - Persons identified as at increased risk because of a serogroup B meningococcal disease outbreak.
- After reviewing the available data, ACIP supported consideration of vaccination of all adolescents rather than college students only, primarily because an important number of serogroup B meningococcal disease cases occurs in persons aged 18–23 years who are not attending college, and vaccinating college students only is estimated to prevent the fewest cases and deaths among all the options considered. However, ACIP also acknowledged the impact that cases and outbreaks have on college campuses, both in terms of the cost for vaccination campaigns in response to these outbreaks as well as public concern. On the basis of the available antibody persistence data, ACIP concluded that a preference to administer the MenB series in later adolescence exists, preferably at age 16–18 years, to maximize the likelihood that protection would last into the highest age-related risk period.

The low prevalence of disease (in Washington State, among 11 to 24 year olds, approximately 2 to 3 cases of meningococcal B disease are detected each year) coupled with the fact that important data for making policy recommendations for MenB vaccines are not yet available, resulted in ACIP determining that insufficient evidence exists to make a routine public health recommendation that all adolescents be vaccinated with MenB vaccine. Given the seriousness of meningococcal disease and the availability of licensed vaccines, ACIP agreed that sufficient evidence exists to encourage individual clinical decision making. Therefore, patients 16 through 23 years of age may be vaccinated with meningococcal B vaccine (preferably at 16 through 18 years of age) to provide short-term protection against most strains of serogroup B meningococcal disease. The permissive recommendation for the use of the vaccine means vaccination is based on individual clinical judgment and discussion with the family.

#### Effectiveness:

The vaccine induces an immune response against most, but not all, circulating meningococcal B strains. No studies have been performed to evaluate the clinical effectiveness of the vaccine.

#### **Duration of Immunity:**

Duration of immunity is unknown. The vaccine provides short term protection against meningococcal B disease.

#### Safety:

There is limited experience with meningococcal B vaccines outside of clinical trials. Current safety concerns include the possible development of an autoimmune response. Post licensure safety surveillance will be important in determining the safety profile for less frequent adverse events. Other vaccine reactions may include syncope, local inflammation at the site of injection, fatigue, headaches, and anaphylaxis.

#### Pregnancy:

No randomized controlled clinical trials have been conducted to evaluate use of MenB vaccines in pregnant or lactating women. Vaccination should be deferred in pregnant and lactating women unless the woman is at increased risk and the benefits of vaccination are considered to outweigh the potential risks.

#### Summary of the two licensed meningococcal B vaccines

Characteristic	Bexsero	Trumenba
Manufacturer	Novartis Vaccines (GSK)	Wyeth (Pfizer) Pharmaceuticals
Licensure	10 through 25 years	10 through 25 years
Schedule	Two doses, at least one month apart (0 and 1 – 6 month schedule)	Three doses (0, 2, and 6 month schedule)
Interchangeability	Must complete series with same product	Must complete series with same product
CPT / CVX Codes	90620 / 163	90621 / 162

Nothing in this guidance supersedes the recommendations of the Advisory Committee on Immunization Practices. Providers should review the complete <u>CDC recommendations</u> for use of meningococcal vaccines for additional details regarding available vaccine products and indications, including use of vaccines in allergic patients and other updated guidance.

#### Ordering from the State Department of Health

Providers in the Childhood Vaccine Program may order meningococcal B vaccine directly from the state as needed. These providers should order sufficient vaccine to complete the series for the patient with the same product.

Contact information for state staff to assist with order placement:

 Phone: 360-236-2VAX (2829). Ask to speak with someone about ordering meningococcal B vaccine. • E-mail: <u>WAChildhoodVaccine@doh.wa.gov</u>

#### **Information for Clinicians:**

- Meningococcal Vaccination: <u>http://www.cdc.gov/vaccines/vpd-vac/mening/default.htm</u> http://www.cdc.gov/vaccines/hcp/vis/vis-statements/mening-serogroup.html
- Interchangeability of Meningococcal Vaccines (may need to copy link into browser): http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm#Box1
- ACIP Meningococcal Vaccine Recommendation: <a href="http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6441a3.htm">http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6441a3.htm</a>

#### Information for Parents:

- Meningococcal B Vaccine Information Statement: <a href="http://www.cdc.gov/vaccines/hcp/vis/vis-statements/mening-serogroup.html">http://www.cdc.gov/vaccines/hcp/vis/vis-statements/mening-serogroup.html</a>
- CDC meningococcal B vaccine materials for parents:
   http://www.cdc.gov/vaccines/vpd-vac/mening/who-vaccinate.htm

Thank you for your partnership.